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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/629,117 | 07/28/2003 | Katsuo Kumagai | 44471/ | 5933 |
| 23370 | 7590 | 03/23/2004 | EXAMINER | |
| JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET SUITE 2800 ATLANTA, GA 30309 | | | KRISHNAN, GANAPATHY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/629,117 | KUMAGAI ET AL. | |
| | Examiner | Art Unit | |
| | Ganapathy Krishnan | 1623 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5 and 11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09995040.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Segal et al (US 4678772).

Claims 1 and 11 are drawn to a therapeutic agent consisting essentially of glycyrrhizin or pharmaceutically acceptable salts thereof and a pharmaceutically acceptable carrier and a therapeutic agent consisting essentially of glycyrrhizin or pharmaceutically acceptable salts thereof, a buffer, a stabilizer, an antioxidant and a pharmaceutically acceptable carrier.

Segal et al teach a composition consisting essentially of glycyrrhizin in an aqueous medium (col. 3, lines 10-13; col. 4, Example 7(b)). The composition also contains sodium fluoride and phosphoric acid which combination would give sodium phosphate, which is a buffer. A buffer is also a stabilizer since it stabilizes by adjusting the pH. Glycyrrhizin itself is an antioxidant. It acts as a radical trap as disclosed by Nagai et al (Japan J. Pharmacol. 1992, 58, 209-218, page 216, right column, see last five lines of the first full paragraph).

This disclosure of Segal et al is seen to meet the limitations of claims 1 and 11. The recitation “for treatment of mastitis” and the therapeutic agent being directly administered into the mammae is intended use and are not given patentable weight.

Art Unit: 1623

Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Shibata et al (JP 1-172332, English Translation).

Claims 3-5 are drawn to a method for treatment of mastitis in cattle comprising administering a therapeutic agent consisting essentially of glycyrrhizin or a pharmaceutically acceptable salt thereof and a carrier; wherein the composition is administered directly to the mammae and wherein the composition is administered during milk secretion period.

Shibata et al teach (see entire document, especially page 1, claim 1; and page 2, detailed explanation of the invention) the treatment of staphylococcal bovine mastitis of cow. They also teach the administration of the extract of *Glycyrrhiza glabra*, one of the ingredients of which is glycyrrhizin (page 3, last paragraph) in crude form or as extracts or in the forms of active ingredients of herbal medicines, or applied as pharmaceutical preparations and injectable preparations (page 6, lines 16-23). The extracts can be prepared using water as the solvent (page 6, line 22). Water is a pharmaceutically acceptable carrier.

Even though Shibata et al state that the extract has additional ingredients like liquiritin, glucose and asparagine, these ingredients are not seen to materially affect the composition or the method of treatment of the said disease. The recitation that glycyrrhizin is directly administered to the mammae during milk secretion period is not given patentable weight. The burden is shifted to the applicants to show that the additional ingredients do materially affect the composition/method seen in the prior art.

Conclusion

Claims 1, 3-5 and 11 are rejected.

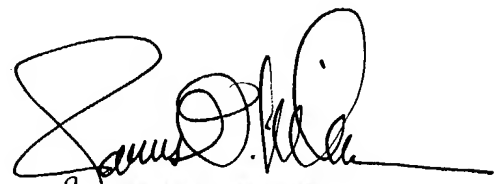
Art Unit: 1623

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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